

Message

From: McAllister, Janet (CDC/OID/NCEZID) [jvm6@cdc.gov]
Sent: 7/12/2016 5:17:32 PM
To: Dass, Brinda (FDA/CVM) [Brinda.Dass@fda.hhs.gov]; Wozniak, Chris [wozniak.chris@epa.gov]; Kough, John [Kough.John@epa.gov]; Mutebi, John-Paul (CDC/OID/NCEZID) [grv0@cdc.gov]
CC: Epstein, Laura (FDA/CVM) [Laura.Epstein@fda.hhs.gov]; Evdokimov, Evgenij A (FDA/CVM) [Evgenij.Evdokimov@fda.hhs.gov]
Subject: RE: Working copy EA 06272016.docx
Attachments: Working copy EA 06272016 jm.docx

Brinda,
I only had a couple of comments early in the document.

Janet McAllister, PhD, BCE

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From: Dass, Brinda (FDA/CVM)
Sent: Monday, June 27, 2016 1:12 PM
To: Chris A Wozniak (wozniak.chris@epamail.epa.gov) <wozniak.chris@epamail.epa.gov>; kough.john@epa.gov; McAllister, Janet (CDC/OID/NCEZID) <jvm6@cdc.gov>; Mutebi, John-Paul (CDC/OID/NCEZID) <grv0@cdc.gov>
Cc: Epstein, Laura (FDA/CVM) <Laura.Epstein@fda.hhs.gov>; Evdokimov, Evgenij A (FDA/CVM) <Evgenij.Evdokimov@fda.hhs.gov>
Subject: Working copy EA 06272016.docx

Dear Chris, John, Janet, and John-Paul:

Please find attached our updated and most current complete version of the Environmental Assessment for Oxitec's OX513A GE mosquito field trial proposed for Key Haven, Florida. Please make your edits and include your comments in track changes mode and email back to me by July 11th, 2016 or sooner. Hopefully your schedules will allow for this really short time frame for commenting on the document. Two points of note-

1. Please ignore the bibliography at the end of the document as we have not yet had time to sort it out. There are duplicates and we will clean this section up in the final document.
2. The sponsor will work with us to provide language that we will insert related to post-trial monitoring of the entire trial site. This will include monitoring immediately following the end of the trial as well as in the next mosquito season (to address the presence of OX513A in egg banks). If you have thoughts specific to post-trial monitoring please let us know so we can make sure they are addressed.

As always if you have any questions please feel free to contact Laura, Evgenij, or myself at any time.

Many thanks.
Brinda

Brinda A Dass, MS, MPH, Ph.D., ALAT

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